REMARKS

Reconsideration of the patentability of applicants' claimed invention is requested respectfully.

Status of the Claims

The Examiner's Final Action addressed all of applicants' pending claims (Claims 18 to 21 and 23 to 45) and constituted a rejection of all of those claims. Claims 18 to 21 and 23 to 37 and 39 to 45 have been cancelled. Claim 38 has been amended. Claims 46 to 57 have been added. Accordingly, there is presented for the Examiner's consideration Claims 38 and 46 to 58, which total in number 14, of which Claim 38 is the only claim which is in independent form. Accordingly, no claim fee is due.

The amendment to Claim 38 includes the subject matter of paragraphs (i) and (ii) of Claim 18 which has been cancelled.

For the Examiner's convenience there are set forth below bases for added Claims 46 to 58, all of which are in dependent form and all of which correspond to a previously pending dependent claim.

Added Claims	Previously Pending Dependent Claims
46	39
47	40
48	41
49	42

50	43
51	44
52	45
53	23
54	24
55	25
56	26
57	27
58	34

The Examiner's attention is directed to applicants' Reply dated March 1, 2005, the paragraph bridging pages 17 and 18 and the last paragraph on page 18, for a summary of applicants' claimed invention.

Summary of the Examiner's Rejections

The Examiner's Action includes a rejection of all of applicants' claims in four different §103(a) rejections which differ one from the other by citation of different combinations of references. By virtue of the claim amendments herein, the only applicable §103(a) rejection is that which the Examiner has asserted against Claim 38. (The other of the Examiner's §103 rejections are not asserted against Claim 38 and all of the claims against which they have been asserted have been cancelled. Accordingly, the only one of the four §103 rejections that needs to be addressed is the §103 rejection of Claim 38.

The Examiner's Action includes also rejections under 35 U.S.C. §112 of Claims 18 to 21, 23 to 45.

The Examiner's §112 and §103 rejections are discussed below.

Discussion of the §112 Rejections

With respect to the Examiner's rejection of independent Claim 18, as mentioned above, Claim 18 has been cancelled and the subject matter of paragraphs (i) and (ii) thereof has been added to independent Claim 38. It is submitted respectfully that the Examiner's rejection of Claim 18 was not proper, as explained below, and, therefore, it is submitted that it is not applicable to amended Claim 38.

The §112 rejection of the claims which define the erythromycin gel as having a viscosity of about 200,000 to about 500,000 cps is traversed respectfully. The Examiner's attention is directed to the present application, page 25, first sentence, which states that particularly preferred embodiments of the invention include gels, each of which has a viscosity of about 200,000 to about 500,000 cps.

With respect to the Examiner's rejection of Claim 23 (now cancelled), the subject matter of which is now set forth in Claim 52, it is submitted respectfully that this subject which has been objected to by the Examiner is referred to in the present application on page 26 at lines 26 to 29.

With regard to the Examiner's rejection of Claims 42, 43 and 39 (now cancelled), the subject matter of these claims is now set forth respectively in Claims 49, 50, and 46 in a form which takes into account the Examiner's objections.

The Examiner's §112 rejection of Claim 38 is addressed after applicants' discussion of the Examiners §103 rejection of Claim 38.

Discussion of the §103 Rejection of Claim 38

The Examiner considers Claim 38 as unpatentable over the disclosure of WO 99/02133 to Lefevre et al in view of the disclosure of WO 97/27841 to Edens et al. The rejection is traversed respectfully.

As mentioned above, the subject matter of Claim 18, as set forth in paragraphs (i) and (ii) thereof, has been incorporated by the present amendment into Claim 38. This subject matter relates to the viscosity of each of the gels referred to in Claim 38 and the concentrations of the ingredients comprising the composition formed from the gels.

The following discussion points out that neither the primary reference (Lefevre et al.) nor the secondary reference (Edens et al.) discloses the "gel" aspects of Claim 38 nor the "package" aspects of Claim 38. Accordingly, the combined disclosures of the primary and secondary references do not result in the subject matter of Claim 38.

With respect to the "gel" aspects of Claim 38 and the Examiner's reliance on the primary reference, applicants acknowledge that this reference does in fact teach gel formulations, as pointed out by the Examiner on page 2 of the Action. However, it is

also a fact that the primary reference does not disclose a gel formulation which contains erythromycin. Please consider the following.

The primary reference discloses various types of compositions differing one from the other depending on the active ingredient included in the composition and that the particular form of the composition depends on the nature of the active ingredient. To wit, the primary reference states the following.

> Thus, the nature of the first and second composition are determined by on the one hand the stability requirements of each individual active ingredient and on the other hand the desired properties of the final composition. (Page 3, lines 13 to 16, of Lefevre et al.)

The "first" composition referred to in the above quotation means a composition containing benzoyl peroxide and the "second" composition means a composition containing a second active ingredient, for example, an antimicrobial agent such as erythromycin, natamycin, clindamycin or lincomycin.

With respect to the "stability requirements", as referred to in the above quotation, for benzamycin, the primary reference refers generally to such compositions on page 5 in the second and third paragraphs; thereafter, the primary reference discloses that one of the embodiments of the various forms of the benzamycin compositions is a gel form (see page 6, lines 19 to 21, and page 7, lines 32 to 35).

However, with respect to an erythromycin-containing composition, there is absolutely no disclosure in the primary reference of such a composition being in the

form of a gel. The primary reference discloses generally that the erythromycin constituent can be used in the form of a solution (for example, dissolved in ethanol) or in the form of a suspension (see the primary reference, page 5, lines 18 to 29). The term "suspension" is a generic term that applies broadly to particles dispensed in a fluid. Accordingly, there are species of suspensions which species are not gels. See Appendix (A) and Appendix (B) which are dictionary definitions respectively of the terms "suspension" and "gel".

Note particularly that the primary reference refers to benzoyl peroxide being in the form of a gel whereas erythromycin is referred to as being dissolved in ethanol in the presence of a thicking agent – no reference to a gel (see the primary reference, page 6, lines 9 to 21). Furthermore, the viscosities of the involved compositions disclosed in the reference are identified as ranging from 100 to 30,000 cps, preferably from 1000 to 10,000 cps, and between 500 and 5000 cps (preferred embodiment disclosed in the reference, page 6, lines 15 and 16), whereas in applicants' claims, the gels have viscosities of at least about 200,000 cps, that is, almost 6.7 times greater than the highest viscosity of the "reference" composition and at least 40 times greater than the viscosity of the preferred embodiment disclosed in the primary reference.

And in addition, Example 1 of the primary reference clearly teaches a composition comprising erythromycin , various solvents, and Carpobol Ultrex viscosifier and that such composition exits in the form of a "...clear solution..." (see the primary reference, the

paragraph bridging pages 8 and 9, and particularly the sentence which bridges page 8 and 9). A clear solution is not a gel.

Page 2 of the Action contains statements to the effect that the primary reference discloses "clearly" an erythromycin composition in gel form; in support of the statements, the Examiner refers to page 8 of the reference. It is recognized that page 8 does in fact disclose an "erythromycin" composition containing Carpobol Ultrez which is described on page 4, lines 21 to 27, of the reference as being a material which is effective in stabilizing a suspension which contains particles or high concentrations of solvents. The Examiner characterizes this "erythromycin" composition as being a gel, whereas the inventors characterize the composition as being a "clear solution" (see page 9, first line of the reference). It is submitted respectfully that the viscosity of the solution was increased by the use of Carpobol Ultrez and, if the "erythromycin" composition were in fact a gel, the inventors would have so characterized the composition and not as being a clear solution.

It is submitted further that an overall reading of the primary reference leads one to conclude that the inventors described various types of compositions containing a viscosifying agent, including: (A) thickened suspensions or solutions which are not in gel form; and (B) compositions which are in gel form and which are so characterized by the inventors, who in no instance characterized an "erythromycin" composition as being in gel form.

To summarize, applicants' Claim 38 distinguishes over the disclosure of the primary reference in at least the following aspects:

(A) in defining erythromycin as being in gel form;

(B) in defining each of the benzoyl peroxide and erythromycin gels as having a viscosity of at least about 200,000 cps (almost 6.7 times higher than the highest viscosity of the reference composition; and

(C) in defining the structure of the package for holding the gels of applicants' invention.

The secondary reference does not disclose any of the above-identified claim recitations, as explained below.

The secondary reference cited in the §103 rejection is International Publication No. WO 97/27841 to Edens et al. The Examiner has cited this reference exclusively for its disclosure relating to the packaging aspects of Claim 38. Thus, at the bottom of page 13 through page 15 of the Action, the Examiner relies on DE 3630849 which is referred to on page 9 of Edens et al. for a teaching of applicants' claimed package. Applicants have reviewed Edens et al. and the U.S. publication which corresponds to DE 3630849, namely U.S. Patent No. 4,823,985. (A copy of this patent was provided to the Examiner in applicants' Reply dated March 1, 2005 – see Appendix B thereof). Nothing relevant has been found in Edens et al that is not in the '985 patent.

In the '985 patent, two embodiments are disclosed. Figure 1, which illustrates the preferred embodiment, is not capable of being folded along a common side contrary

to the Examiner's statement. There are no common sides in Figure 1 of the '985 patent, and even if there were, the two adjacent sides of chambers 2 and 3 would not be capable of being folded in the manner disclosed and claimed by applicants. The remaining embodiment found in the '985 patent does show, in Figure 2, a common wall 104 dividing the two compartments as shown in cross-section. However, there is no teaching or suggestion of how wall 104 might be folded. There is no mention of folding at all in the text of the patent. There would be no reason for folding as called for in Claim 38 since the portions of the packets of the reference from which the dispersing orifices are formed are already adjoining one another. Accordingly, the "package" aspects of applicants' Claim 38 distinguish over the Edens et al. disclosure and the '985 patent.

In summary, the combined disclosures of the primary and secondary references do not disclose either the "gel" aspects, the viscosity aspects, or the "package" aspects of Claim 38. Accordingly, it is requested that the involved §103 rejection be withdrawn.

Discussion of the Examiner's §112 Rejection of Claim 38

The present amendment to Claim 38 modifies the claim to recite viscosity ranges for the gels referred to therein and amount ranges for the benzoyl peroxide and erythromycin constituents comprising the gel composition defined in Claim 38.

As regards other of the Examiner's comments respecting Claim 38, the

Examiner's attention is directed to the present application and the paragraph bridging pages 23 and 24, and particularly the last complete sentence on page 23 and continuing through the end of the paragraph on page 24.

The volume of composition dispensed from the packet is dependent on not only the force applied, but also on the viscosity of the composition.

In view of the above it is requested respectfully that the application be allowed in an early and favorable Action.

Respectfully submitted,

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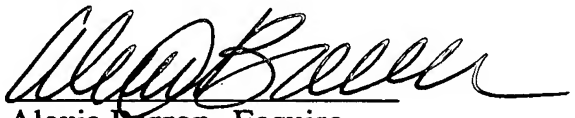

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